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Applicant:	Bannon, et al.	Examiner:	Huynh, P.
Serial No.:	09/494,096	Art Unit:	1644
Filed:	January 28, 2000		
For:	METHODS AND REAGENTS FOR DECREASING CLINICAL REACTIONS TO ALLERGY		

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REPLY BRIEF UNDER 37 C.F.R. § 1.193

Appellant offers the present comments in Response to the Examiner's remarks in the Answer mailed August 10, 2005. Most of the Examiner's remarks in this Answer were restatements of previously-articulated positions, but some points were new; if a given item is not specifically discussed herein, then the Examiner has not presented new points of argument and/or Appellant relies on the arguments made in the Appeal Brief.

For ease of presentation, Appellant's comments in this Reply Brief are organized according to the headings and numbered issues presented in Appellant's Appeal Brief submitted July 8, 2004 (the "Brief"). For the convenience of the Board, references to pages within the Examiner Answer are also included.

The deadline for filing a Reply Brief is October 10, 2005. Applicant thus submits that the present Reply Brief is timely filed on October 4, 2005.

Issues

Appellant acknowledges and thanks the Examiner for withdrawing the rejection of claims 41-42 under 35 U.S.C. § 112, second paragraph, namely Issue # 4 in Appellant's Brief (see page 2 of Examiner's Answer). Issues # 1-3 and 5-7 remain.

Argument

ISSUE 1: Claims 37-46 and 56-61 are not invalid for lack of enablement

(A) In her Answer, the Examiner continues to articulate a breathtaking new enablement standard. According to this Examiner, it is not possible to enable a claim to a genus of nucleotide molecules unless the complete sequence of *every* nucleotide molecule that falls within the scope of the claim is explicitly set forth in the application. Specifically, on several occasions in the Answer, the Examiner makes the following statement:

> "Until the nucleotides or codon corresponding to the amino acid residue(s) in the at least one IgE epitope essential for IgE antibody binding in *all* food allergen have been identified and the corresponding amino acids to be substituted for said amino acid residue(s) in the at least one IgE epitope, the specification merely extends an invitation for one skilled in the art to further experimentation to arrive at the full scope of the claimed invention" (emphasis added, see pages 8 and 25).

Appellant respectfully submits that the legal standard put forth by the Examiner in these remarks bears no relationship whatsoever to the standard that has been set forth in *Wands*, or in any other case. *Wands*, like all other enablement decisions, holds that a claim is enabled so long as no *undue experimentation* is required to practice the claimed invention to the scope of the claim. By contrast, this Examiner says that a claim cannot be enabled unless *absolutely no* experimentation is required. This is not, and should not be, the standard.

(B) The Examiner also makes the following novel point regarding nucleotide molecules that encode modified peanut allergens:

> "Even if the nucleotide molecule is limited to modified peanut allergens, there is no in vivo working example using polynucleotide for treating peanut allergy (gene therapy)" (*emphasis* added, see pages 5 and 18).

Appellant does not see the relevance of this statement. The existence of *in vivo* working examples *might* be relevant if Appellant were claiming methods of gene therapy; however, as repeatedly noted by the Examiner, the pending claims are drawn to nucleotide molecules that

encode modified food allergens (or modified peanut allergens under the Examiner's hypothetical). Alternatively, such working examples could possibly have been relevant if Appellant had failed to provide any utility for the claimed nucleotide molecules; however, as demonstrated in the specification, the claimed nucleotide molecules are useful, e.g., in the preparation of modified food allergen proteins (or modified peanut allergens) that can be used to desensitize allergic patients. Accordingly, Appellant respectfully submits that the quoted statement has no place in the Examiner's argument.

ISSUE 2: Claims 37-46 and 56-61 are not invalid for lack of written description

As discussed in the Brief, the Examiner adopts the same standard for written description as she does for enablement. Specifically, she states:

> "There is inadequate written description about the structure of all nucleotide molecule [sic] encoding any modified food allergen because of the following reasons: A nucleotide molecule without the nucleotide sequence, the corresponding SEQ ID NO has no structure" (see pages 9 and 34; see also pages 10 and 35, which repeat the assertion that "polynucleotide molecules without SEQ ID NO has [sic, have] no structure").
>
> As with enablement, it is apparently the Examiner's position that the written description requirement can never be satisfied for *any* nucleic acid or protein unless the complete sequence is explicitly set forth in the specification and recited in the claim by way of a SEQ ID NO.

This is clearly not the law nor should it be. The proper legal question is not "did Appellant *reduce to practice* and *explicitly recite* every modified peanut allergen that falls within the scope of the claims?" Instead, the question is "would a skilled person recognize that Appellant was in *possession* of the modified peanut allergens that fall within the scope of the claims?" As set out in the Brief it is Appellant's position that a skilled person would readily recognize that Appellant was in possession of the full scope of the claims.

ISSUE 5: Claims 37-45 and 56-61 are not obvious in light of Burks et al. (1997) and Evens et al. (1993)

On page 40, the Examiner argues again that this rejection under 35 U.S.C. § 103(a) is proper. Appellant respectfully disagrees – it is an axiom of patent law that a prior art reference cannot be used to anticipate an invention if the teachings of that prior art reference were included in the patent application or the patent application properly claims priority to such an application. As noted in the Brief, the teachings of Burks et al. (1997) were included near *verbatim* in priority documents U.S. Serial No. 08/717,933 filed September 23, 1996 (see pp. 135-155, 175, and 178-180, the "1996 filing") and U.S. Serial No. 09/141,220 filed August 27, 1998 (see pp. 7-11 and 16-29, the "1998 filing"). The present application properly claims priority to the 1996 filing via the 1998 filing. Burks (1997) et al. was published after the 1996 priority date and cannot therefore be used as prior art under 35 U.S.C. § 103(a). Withdrawal of the rejection is earnestly requested.

ISSUE 6: Claims 37-46 and 56-61 are not obvious in light of Stanley et al. (1997) and Evens et al. (1993)

On page 41, the Examiner argues again that this rejection under 35 U.S.C. § 103(a) is proper. Appellant respectfully disagrees for the same reasons as above. As noted in the Brief, the teachings of Stanley et al. (1997) were included near *verbatim* in priority documents U.S. Serial No. 08/717,933 filed September 23, 1996 (see pp. 156-174 and 176-180, the "1996 filing") and U.S. Serial No. 09/141,220 filed August 27, 1998 (see pp. 7-11 and 16-29, the "1998 filing"). The present application properly claims priority to the 1996 filing via the 1998 filing. Stanley et al. (1997) et al. was published after the 1996 priority date and cannot therefore be used as prior art under 35 U.S.C. § 103(a). Withdrawal of the rejection is earnestly requested.

Conclusion

For all of these reasons, Appellant respectfully submits that the pending claims are fully supported by the specification as filed and allowable over the art of record. The Examiner's rejections should be reversed.

Respectfully submitted,

October 4, 2005

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